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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 12/12/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,946

Applicant(s)

CHAUVEAU ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 August 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 9-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 9-20 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

Claims 9-20 are included in the prosecution of this application.

Preliminary Amendments and Priority Dates are acknowledged.

The references cited in the Search Report have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The

Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation of "polyol having less than 13 carbons", and the claim also recites polyol being selected from mannitol, xylitol, sorbitol, and maltitol" which is the narrower statement of the range/limitation.

The proper Markush language is "selected from the group *consisting of...*" in claim 1.

The language "it being understood that..." is confusing since it is unclear what is the claimed invention is.

The recitation of "compressible form and the other is in powder form" in claim 1 is indefinite since it is not clear whether one of the diluent agents is already in a compressed form. If it is not compressed, what is the difference between the compressible form and the powder form which can be compressed too? Also, the language "whereas in the case..." is indefinite since it is unclear whether claimed invention contains one or two diluent agents.

Regarding claim 1, the phrase "advantageously" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Regarding claim 15, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Examiner suggests restructuring claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghanta et al (5814332) by itself or in view of Gergely et al (5064656).

Ghanta et al teaches a composition containing ibuprofen, granular mannitol, crospovidone, colloidal silica, magnesium stearate, and aspartame (Note example 2).

The particle size taught is between 25-600 microns (col. 3, line 62).

Ghanta et al does not teach the dissolution time or instant ratio.

Gergely et al teaches 30-60 second disintegrating tablet containing ibuprofen, Aerosil (fumed silica), PVPP, lactose, and saccharin (Example 41). The reference also teaches the use of mannitol (Example 39) and the optional use of a lubricant such as magnesium stearate (Example 45). Gergely et al teaches the instant ratio of excipient to actives to obtain a fast disintegrating tablet and varying dissolution time by manipulating the amount of components (Example 10-14).

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the conditions of Ghanta et al since the reference provides the general guidance for making the composition containing the instantly claimed compounds. One would be motivated to do so since the dissolution rate depends on the proportion of the compounds in the composition, for faster dissolution one would be motivated to increase the amount of disintegrating agent; thus manipulation of these components would yield the desired dissolution rate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ghanta et al and Gergely et al. One would be motivated to do so since Gergely et al provides the general guidance of a fast disintegrating tablet and Ghanta et al teaches the instantly claimed composition. Further motivation to use Gergely et al is that the reference teaches all of the instantly claimed compounds and different combinations of the compounds.

Claims 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geyer et al (5320848) in view of Meyers et al (5567439).

Geyer et al teach a rapidly disintegrating chewable tablet containing mannitol, ibuprofen, magnesium stearate, sweeteners, and flavors (Example 10). Further, the reference discloses the general composition containing a drug, one or more granulating agents, a rapid dispersal agent, and additives (col.6, lines 44-65 and claims). Geyer et al teach the combination of mannitol and sorbitol and dispersal agents such as crosmellose sodium and crospovidone (Note examples and claim 2). Particles read on instantly claimed size (col.4, lines 14-15).

Geyer et al does not teach the use of silicon.

Meyers et al teach a quick dissolve tablet (Note abstract). Meyers et al teach glidants such as silica aerogels are useful for tabletting because they reduce interparticle friction and therefore increase flow properties (col. 13, lines 55-65).

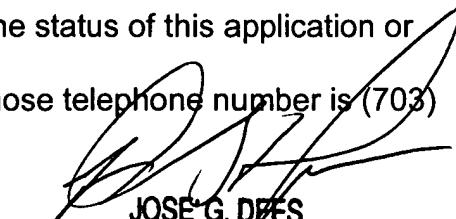
It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Geyer et al and Meyers et al since both of the references teach fast dissolving tablets. One would be motivated to use silicon in Geyer et al's composition since silicon allows liquid to flow through the tablet letting it dissolve quicker.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to manipulate the conditions of Gergely et al and substitute mannitol for lactose since the expectation of a similar effect is reasonable because lactose is a sugar. One would have been motivated since Gergely et al provide the

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.


JOSE G. DEES
SUPERVISORY PATENT EXAMINER


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